



4164-04-P

## REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

[BAC 416404]

### Annual Public Meeting

**ACTION:** Notice of annual meeting.

**SUMMARY:** The Reagan-Udall Foundation for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Administration Amendments Act of 2007, is announcing its annual public meeting. The purpose of this meeting is to provide an opportunity for the Foundation to engage with its stakeholders and receive public input on its efforts. The meeting will include an organizational update, project updates, open Q & A and the opportunity for public commentary.

**DATES:** The public meeting will be held on May 26, 2016, from 10 a.m. until 12 noon.

Registration to attend the meeting and requests for oral presentation must be received by May 18, 2016. See the SUPPLEMENTARY INFORMATION section for information on how to register for the meeting.

**ADDRESSES:** The public meeting will be held at 901 E St. NW., Washington, DC 20004.

Entrance for the meeting is located on 9<sup>th</sup> St. NW., between F St. NW. and E St. NW.

**FOR FURTHER INFORMATION CONTACT:** Dr. Nancy Beck, Reagan-Udall Foundation for the FDA, 202-828-1205, [Meetings@ReaganUdall.org](mailto:Meetings@ReaganUdall.org).

### SUPPLEMENTARY INFORMATION:

#### I. Background

The Reagan-Udall Foundation for the FDA (the Foundation) is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of FDA to modernize

medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research projects to advance regulatory science.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how Reagan-Udall Foundation projects can help the Agency to fulfill its mission.

The Foundation's programmatic efforts are designed to improve the existing scientific tools (methods) used to evaluate products as well as foster the development of innovative tools and approaches. This is exemplified in the Foundation's projects including: The Innovation in Medical Evidence Development and Surveillance (IMEDS) Program, which develops and evaluates methods for using observational electronic health care data for postmarket evidence generation, including postmarket safety surveillance; the Big Data for Patients (BD4P) Program, which is a data science training program for patient advocates in the science, concepts, uses, and impact of big data on patients; and the Critical Path to Tuberculosis Drug Regimens Project, which looks at novel approaches to development and review of tuberculosis combination therapies, including strategies for engaging communities in the research process. The Foundation is currently exploring potential new projects as well. One of those projects is the Food Safety Innovation Consortium, to advance regulatory science in the food safety arena. Another area under development involves examining ways to improve the availability and clarity

of information on the request process for individual expanded access (compassionate use) for drugs that have not yet been approved by the FDA.

## II. Meeting Attendance and Participation

### A. Registration

If you wish to attend the meeting, visit: <http://bit.ly/1RRSqjp>. Please register for the meeting by May 18, 2016. Seating is limited and registration will be on a first-come, first-served basis.. Onsite registration will be available if space permits. There is no fee to attend this workshop.

### B. Requests for Oral Comments

Interested persons are welcome to present comments at the public meeting, provided they are submitted by May 18, 2016. Comments are scheduled to begin approximately at 11:40 am. Time allotted for comments may be limited to 3 minutes, dependent upon the number of requests received. Submissions must include: your name, organization, address, telephone number, email, and a brief statement on the general nature of your comments. All submissions should be sent to: [comments@reaganudall.org](mailto:comments@reaganudall.org), please specify “**RUF Public Meeting Comments**” in the subject line.

The agenda for the public meeting will be posted on the event page on the Reagan-Udall website: <http://bit.ly/1UZnfcB>.

### C. Written Comments

Interested persons may submit either electronic or written comments to the Foundation at any time to [comments@reaganudall.org](mailto:comments@reaganudall.org), or by mail to the Reagan-Udall Foundation for the FDA, 1025 Connecticut Ave. NW., Suite 1000, Washington, DC 20036. Please include your name, organization, address, telephone number, and email when making comments.

### III. Post-Meeting Materials

The Foundation plans to make meeting materials and meeting recording available to the public after the meeting. Once available, these materials will be posted on the Reagan-Udall website: <http://bit.ly/1UZnfcB>.

Dated: April 11, 2016.

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Nancy Beck,

Acting Deputy Director,

Reagan-Udall Foundation for the FDA.

[FR Doc. 2016-08656 Filed: 4/13/2016 8:45 am; Publication Date: 4/14/2016]